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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,348	06/14/2002	Max Gregor Paping	702-011892	3813
7590	10/01/2004		EXAMINER	
Barbara E Johnson 700 Koppers Building 436 Seventh Avenue Pittsburgh, PA 15219-1818			KHARE, DEVESH	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 10/01/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,348

Applicant(s)

PAPING ET AL.

Examiner

Devesh Khare

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-46, 52 and 53 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-46, 52 and 53 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Applicant's Amendment and remarks filed on 04/19/2004 are acknowledged. Claims 36-38, 41 and 42, have been amended. New claims 52 and 53 have been added.

Claims 47-51 have been withdrawn from consideration as being elected to nonelected subject matter. The rejection of claims 36-46, under 35 U.S.C., 112, second paragraph, has been overcome through applicants' amendment to the claims.

Claims 1-35 have been cancelled. The rejection of claims 42-46, under 35 U.S.C., 102(b), has been overcome through applicants' amendment to the claims.

Claims 1-35 have been cancelled.

The examiner withdraws the 35 U.S.C. 103(a) rejection, as being unpatentable over unpatentable over Stockum (4,143,109) in view of Fitt et al. (U.S. Patent 5,385,608) in response to applicant's remarks that "the starch disclosed in the Fitt patent is incorporated in the rubber latex as a loose layer of powder and not into the liquid rubber latex as in the claimed invention."

During the course of reconsideration of the application, a prior art reference not previously applied in the 35 U.S.C. 103(a) rejection is applied here (see rejection below).

Claims 36-46, 52 and 53 are currently pending in this application.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claim 40 and 53 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) Claim 40, depends on the method claims 36 and 39, is directed to the method for reducing the allergen activity of rubber latex. The recitation in a dependent claim of "the source of an active agent" or modified starch to be used in a method from which said claim depends, wherein "the source of said active agent" does not result in a patentably distinguishable methodological and manipulative difference in how said active agent's source impacts the method from which it depends, renders the claim 40 in which it occurs and which depend therefrom indefinite for failing to distinctly articulate how such a recitation further limits the method from which said dependent claim 40, applicant regards as the invention.

(B) Claim 53 does not confer patentable distinction on the previously claimed rubber latex article of claim 42 therefore claim 53 is a substantial duplicate of claim 42. Claim 53 fails to further limit invention of claim 42. The preamble of the product claim 53 provides a process therefore does not limit the claim.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims **36-41 and 52** are rejected under 35 U.S.C. 103(a) as being unpatentable over Stockum (4,143,109) in view of Dove (U.S. Patent 5,691,446).

Claims 36-41 and 52 are drawn to the method for reducing the allergen activity of rubber latex comprising incorporating an amount of starch into the liquid rubber latex before forming the article. Additional claim limitations include the allergen activity of said rubber latex is maximally 20% and 50%, of the allergen activity of rubber latex without starch; starch is modified by gelatinizing the starch and subsequently crosslinking the starch with glyoxal; the allergen activity of rubber latex containing modified starch is maximally 5%, 15% and 40%.

Stockum teaches a method for producing rubber latex in combination with starch (abstract). Stockum discloses the natural rubber latex in combination with an epichlorohydrin cross-linked corn starch (col. 4, lines 22-26) and its use in medical glove and other articles (col. 4, lines 41-43). Stockum also discloses a method wherein a part of fluid latex is mixed with cross-linked corn starch and used to cover a preformed latex gloves (col. 4 and 5, Example 1). It is noted that the method of producing rubber latex as disclosed in the prior art is not seen to impact the incorporation of the starch in the final product. Stockum differs from the applicant's invention in that Stockum does not provide an explicit example of how the rubber latex article is formed from the mixture of starch and a rubber latex.

Dove also discloses the manufacturing protocols such as dip-forming or other standard protocols for incorporating biopolymer into the rubber latex (col.8, lines 60-65).

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Dove discloses a method for producing "hypo" or reduced allergenic natural rubber latex articles (col. 4, lines 27-46). Furthermore, Dove discloses that biopolymers (screening agents) can be used to reduce the allergenicity of the natural rubber latex articles (col. 6, lines 5-7 and col. 9, lines 50-60). The screening reagents may range from 0.1 to 10 wt % (col. 6, lines 20-25). Dove discloses the production of rubber latex articles such as gloves, inflatable balloons and condoms (col. 7, lines 14-22 and col. 8, lines 36-37). It is noted that the disclosed allergen activity in the prior art is not correlated to any specific amount of starch.

Therefore, one of ordinary skill in the art would have found the applicants claimed method for producing rubber latex in combination with a modified starch or starch, to have been obvious at the time the invention was made having the above-cited references before him. Since Stockum teaches a method for producing rubber latex in combination with the cross-linked starch and Dove discloses that biopolymers (screening agents) can be used to reduce the allergenicity of the natural rubber latex articles, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a rubber latex comprising an amount of starch or modified starch. Stockum provides the motivation to produce a "powderless glove" for surgery, thus avoiding allergen activity caused by powdery starch in a rubber latex glove (col.1, lines 45-51).

Indeed, the examiner has established a prima facie case of obviousness rendering claims 1-14 rejected under 35 U.S.C. 103(a) by addressing sufficiently all of the limitations set forth in the instant process for the preparation of an orally administrable

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calcium composition, one skilled in the art would have a reasonable expectation for success in combining the teachings of Valentine and Walsdorf references to accomplish a process for the preparation of a tablet having a calcium compound such as calcium carbonate used as an active ingredient (Valentine) wherein the compressibility of the said compound in terms of particle size and surface area is determined by the X-ray data because these data are useful in the preparation of more soluble and bioavailable calcium composition (Walsdorf).

Claims **42-46 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Dove (U.S. Patent 5,691,446) in view of Stockum (4,143,109).

The applicants' claims 42-46 are directed toward rubber latex article comprising rubber latex having reduced allergen activity comprising an amount of starch wherein said amount is maximally 10 wt%. Claim 53 is drawn to the rubber latex article of claim 42.

How the said rubber latex articles are prepared is not given patentable weight.

Additional claim limitations include the rubber latex articles surgical glove, condom and inflatable balloon.

Stockum teaches a method for producing rubber latex in combination with starch (abstract). Stockum discloses the natural rubber latex in combination with an epichlorohydrin cross-linked corn starch (col. 4, lines 22-26) and its use in medical glove and other articles (col. 4, lines 41-43). Stockum also discloses a method wherein a part of fluid latex is mixed with cross-linked corn starch and used to cover a preformed latex gloves (col. 4 and 5, Example 1). It is noted that the method of producing rubber latex

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as disclosed in the prior art is not seen to impact the incorporation of the starch in the final product. Stockum differs from the applicant's invention in that Stockum does not provide an explicit example of how the rubber latex article is formed from the mixture of starch and rubber latex.

Dove discloses the reduced allergenicity natural rubber latex articles (see abstract). Dove discloses a method for producing "hypo" or reduced allergenic natural rubber latex articles (col. 4, lines 27-46). Furthermore, Dove discloses that biopolymers (screening agents) can be used to reduce the allergenicity of the natural rubber latex articles (col. 6, lines 5-7 and col. 9, lines 50-60). The screening reagents may range from 0.1 to 10 wt % (col. 6, lines 20-25). Dove also discloses the manufacturing protocols such as dip-forming or others for incorporating biopolymer into the rubber latex (col.8, lines 60-65). Dove discloses the production of rubber latex articles such as gloves, inflatable balloons and condoms (col. 7, lines 14-22 and col. 8, lines 36-37). It is noted that the disclosed allergen activity in the prior art is not correlated to any specific amount of starch.

Therefore, one of ordinary skill in the art would have found the applicants claimed rubber latex article comprising rubber latex having reduced allergen activity comprising an amount of starch wherein said amount is maximally 10 wt%, to have been obvious at the time the invention was made having the above-cited references before him. Since Stockum teaches a method for producing rubber latex in combination with the cross-linked starch and Dove discloses that biopolymers (screening agents) can be

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incorporated into the rubber latex to reduce the allergenicity of the natural rubber latex articles, one skilled in the art would have a reasonable expectation for success in combining both references to obtain a rubber latex article comprising an amount of starch or modified starch. Stockum provides the motivation to produce a "powderless glove" for surgery, thus avoiding allergen activity caused by powdery starch in a rubber latex glove (col.1, lines 45-51).

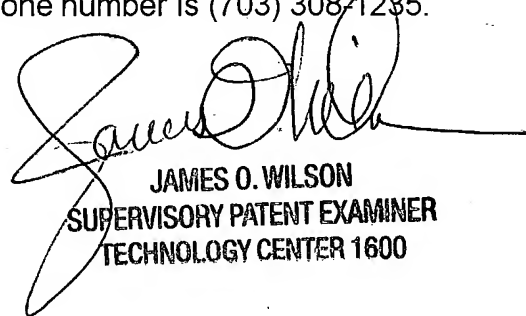
In the absence of data to correlate the amount of starch to reduced allergen activity, the art of record is seen to render the instant methods of claims 36-41 and 52 and products of claims 42-46 and 53, prima facie obvious.

Any inquiry concerning this communication or earlier communications from the

Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D., J.D.
Art Unit 1623
September 21, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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